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Guidelines for cleaning, disinfection, and sterilization of transducers

This manual describes the cleaning, disinfection, and sterilization procedures for the ultrasound transducer. For the operating precautions and procedures for the transducers, refer to the operation manual for each transducer.


Safety Precautions

1. Meaning of Signal Words

In this manual, the signal words **DANGER**, **WARNING**, **CAUTION** are used regarding safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

Signal word	Meaning
 DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
 WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in property damage.


2. Meaning of Safety Symbols

Symbol	Description
	"ATTENTION" (Refer to the operation manual.)

3. Safety Precautions

Observe the following precautions to ensure the safety of patients as well as operators when performing cleaning, disinfection, or sterilization of the transducer.

 **CAUTION:**
Federal law restricts this device to sale by or on the order of a physician.

 **WARNING:**

- Never immerse the transducer connector or any other non-waterproof sections into liquids such as water or cleaning solution. Immersion may cause electrical shock. Refer to the figures on the last page for the immersible range of each transducer model.
- Handling the cord on this product will expose you to lead, a chemical known to the State of California to cause birth defects or other reproductive harm.
Wash hands after handling.

CAUTION:

- Precautions concerning cleaning, disinfection, and sterilization.
 - Observe the following precautions to prevent infection.
 - Wear protective gloves when performing cleaning.*
 - Wear sterile protective gloves when performing disinfection or sterilization.*
 - Wear new protective gloves each time cleaning, disinfection, and sterilization are performed.
 - Clean the transducer before and after examination. Disinfect or sterilize the transducer as required.
 - Sterilize the transducer and biopsy adaptor before and after an ultrasound-guided biopsy procedure is performed. Failure to do so may result in the transducer and biopsy adaptor becoming sources of infection.
 - * Refer to the FDA's March 29, 1991 Medical Alert on Latex Products.
 - After cleaning, rinse the transducer thoroughly with purified water to remove all chemical residues. After disinfection, rinse the transducer thoroughly with sterile or deionized water to remove all chemical residues. Chemical residues on the transducer may be harmful to the human body.
 - After chemical cleaning or chemical disinfection, thoroughly dry the transducer surface.
 - After sterilization, degas the transducer. Gas residues on the transducer may be harmful to the human body.
 - The efficacy of the cleaning solutions, disinfectants, and sterilizing gases is not guaranteed by TOSHIBA. Contact the manufacturers for information on the activity of the products.

CAUTION:

- To ensure the prevention of infection, confirm the effectiveness of each chemical for cleaning, disinfection, or sterilization based on the criteria (such as effective period, number of times of use, discoloration, and results of using the effectiveness test kit) described in the documentation provided by the relevant manufacturer.
- Observe the following precautions to prevent transducer malfunction.
 - The transducer must not be immersed in a chemical solution for more than three hours.
 - Do not permit the transducer to become overheated (more than 60°C) during cleaning, disinfection, and sterilization.
 - Repeated cleaning, disinfection, and sterilization will eventually damage the transducer. Minimize disinfection and sterilization.
 - The cleaning, disinfection, or sterilization conditions, such as the temperature and pressure, differ depending on the product. In addition, some products cannot be subjected to disinfection or sterilization procedures. Confirm the detailed conditions by referring to the table on the last page.

NOTE:

The mouthpiece supplied with the TEE transducer can be boiled or autoclaved (temperature: 134°C, holding time: 5 min). Confirm that "AUTOCLAVABLE" is indicated on the mouthpiece.

Cleaning

- <<Items to be used: Protective gloves, cleaning solution, purified water, sterile cloth or gauze, single-use sponge>>
- Wear protective gloves to prevent infection. Wear new protective gloves each time cleaning is performed.
 - Wash off all organic materials (such as blood or other bodily fluids) from the transducer under purified water. A single-use sponge can be used for washing. Do not use a brush, because it may damage the transducer.
 - Immerse the transducer in a cleaning solution shown in the table on the last page to dissolve or remove all remaining organic materials. Use a single-use sponge if necessary. If dried organic materials are present on the transducer, immerse it in the cleaning solution for a prolonged period.
 - Remove all residual organic materials and cleaning solution from the transducer by rinsing it under purified water. Confirm that all organic materials and cleaning solution have been completely removed. Do not reuse the purified water.
 - Dry the surface of the transducer using sterile cloth or gauze. Do not use heat to dry the transducer.

Handle the cleaning solution as described in the documentation provided by the relevant manufacturer. To maintain the effectiveness of the cleaning solution, ensure that the concentration, temperature, and other conditions specified in the documentation provided by the manufacturer are met. To confirm the effectiveness of the cleaning solution, use the criteria (such as effective period, number of times of use, discoloration, and results of using the effectiveness test kit) described in the documentation provided by the manufacturer.

Sterilization

Before sterilization, the transducer must be cleaned.

<<Items to be used: Sterile protective gloves, sterilant>>

- * Some types of transducers cannot be sterilized or the sterilization conditions may differ.
- Wear sterile protective gloves to prevent infection. Wear new sterile protective gloves each time sterilization is performed.
 - Sterilize the transducer using the chemicals listed on the last page.
 - When EOG sterilization involving prevacuuming or hydrogen peroxide plasma sterilization is to be performed, place the transducer in a sterilization packing case and then place it in the sterilizer.
 - After gas sterilization, perform aeration to remove all gas residues on the transducer surface.

Disinfection

Before disinfection, the transducer must be cleaned.

- <<Items to be used: Sterile protective gloves, disinfectant, sterile or deionized water, sterile cloth or gauze>>
- Wear sterile protective gloves to prevent infection. Wear new sterile protective gloves each time disinfection is performed.
 - Disinfect the transducer using the disinfectants shown in the table on the last page.
 - Rinse off all residual disinfectant from the transducer with sterile or deionized water. Confirm that the disinfectant has been completely removed. Do not reuse the sterile or deionized water.
 - Dry the surface of the transducer using sterile cloth or gauze. Do not use heat to dry the transducer.

Handle the disinfectant as described in the documentation provided by the relevant manufacturer. To maintain the effectiveness of the disinfectant, ensure that the concentration, temperature, and other conditions specified in the documentation provided by the manufacturer are met. To confirm the effectiveness of the disinfectant, use the criteria (such as effective period, number of times of use, discoloration, and results of using the effectiveness test kit) described in the documentation provided by the manufacturer.

<div>Precautions for use</div> <div><ul style="list-style-type: none">Wear protective gloves when performing cleaning.*Wear sterile protective gloves when performing disinfection or sterilization.*Wear new protective gloves each time cleaning, disinfection, or sterilization is performed.After chemical cleaning, rinse the transducer thoroughly with purified water and then dry it.After chemical disinfection, rinse the transducer thoroughly with sterile water or deionized water and then dry it.</div> <div>* Refer to the FDA's March 29, 1991 Medical Alert on Latex Products.</div> <div>Efficacy and effectiveness of the cleaning, disinfection, and sterilizing agents</div> <div><ul style="list-style-type: none">Contact the manufacturer of the relevant chemical for the efficacy of each cleaning, disinfection, or sterilizing agent.Determine the effectiveness of each agent based on the criteria described in the documentation supplied with the agent.</div>		Usable chemicals																	
		Cleaning							Disinfection									Sterilization	
	Chemical name/type	Enzyme					Ethyl alcohol	Isopropyl alcohol	Glutaraldehyde								Ortho-phthalaldehyde	Ethylene oxide gas ^{*1}	Hydrogen peroxide plasma ^{*2}
	Trade name	CIDEZYME®	MetriZyme®	Rapid Multi-Enzyme cleaner	Klenzyme®	Instru-Zyme™ Gel	Ethanol	Isopropyl alcohol	CIDEX®	CIDEX PLUS® 28 day solution	MetriCide®	MetriCide® 28	MetriCide® Plus 30	WAVICIDE®-01	Sporicidin®	CIDEX® OPA	Ethylene oxide gas	STERRAD® 50, 100, 100S, 200	
	Manufacturer	J&J	Metrex Research, Inc.	3M Company	STERIS Corporation	Micromedics Inc.			J&J	J&J	Metrex Research, Inc	Metrex Research, Inc	Metrex Research, Inc	Medical Chemical Corporation	Sporicidin International	J&J		J&J	
	Concentration (Dilution ratio)	0.8% (125)	0.77% (130)	1% (100)	0.8%(125)	working solution	80% (original solution)	70% (original solution)	2.4% (working solution)	3.4% (working solution)	2.6% (working solution)	2.5% (working solution)	3.4% (working solution)	2.5% (working solution)	1.12% (working solution)	0.55% (working solution)	10%	Use the sterile cartridge specifically designed for each sterilizer. There are no sterilization-related parameters (temperature, humidity, pressure, or time) to be set by the operator.	
	Time	1 min.	5 min.	10 min.	5 min.	Wiping only	Wiping only	Wiping only	120 min.	20 min.	45 min.	90 min.		45 min.	20 min.	12 min.	Exposure time: 7 hours Aeration time: 12 hours		
	Temperature	Room temperature	Room temperature		Room temperature	Room temperature	Room temperature	Room temperature	Room temperature		Room temperature			Room temperature	Room temperature	Room temperature	50°C		
	Humidity	Normal humidity	Normal humidity		Normal humidity	Normal humidity	Normal humidity	Normal humidity	Normal humidity		Normal humidity			Normal humidity	Normal humidity	Normal humidity	50%		
	Pressure	Normal pressure	Normal pressure		Normal pressure	Normal pressure	Normal pressure	Normal pressure	Normal pressure		Normal pressure			Normal pressure	Normal pressure	Normal pressure	Operating pressure 980 hPa [gauge]		
Model name ^{*3}																			
PC-20M	Immersible range	OK	OK	OK	OK	–	OK	OK	OK	–	OK	OK	OK	–	–	–	–		
	Type A																		
PC-50M	Type A	OK	OK	OK	OK	OK	OK	OK	–	OK	OK	OK	–	OK	–	–	–		
PET-508MA ^{*4}	Type B	OK	OK	–	–	OK	–	OK	OK	OK	OK	OK	–	OK	–	–	–		
PET-511BTM ^{*4} /510MB ^{*4}	Type C	OK	OK	OK	–	OK	–	OK	OK	OK	OK	OK	OK	OK	–	–	–		
PLT-308P/604AT/704AT/805AT PLT-1202S/1204AT/1204AX PLT-1204BT/1204BX	Type D	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
PST-20CT/25AT/25BT PST-37CT/50AT/65AT																			
PVT-375AT/375AX/375BT PVT-382BT/674BT																			
PVT-661VT/770RT																			
PLT-705BTF/705BTH, PVT-745BTV	Type D	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
PVT-350BTP	Type D	OK	OK	–	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
PLT-704SBT	Type D	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	–	OK	OK		
PST-25SX	Type D	OK	OK	–	OK	OK	OK	OK	–	–	OK	OK	OK	–	–	–	–		
PST-30BT/30SBT	Type D	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	–		
PLT-1204MV, PVT-382MV/575MV	Type D	OK	OK	–	OK	OK	OK	OK	OK	OK	OK	OK	–	OK	–	–	–		
PVT-681MV	Type D	OK	–	–	–	OK	OK	OK	–	–	–	–	OK	–	–	–	–		

OK: Use of the chemical is permitted.

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 : Use of the chemical is not permitted.

*1 : After sterilization, thoroughly degas the transducer to remove all gas residues on the transducer.

*2 : Note that the label on the transducer may fade and the connector handle may become difficult to turn. These are not abnormalities.

*3 : When multiple model names are referred to, they are abbreviated. For example, "PST-50AT and PST-65AT" is abbreviated as "PST-50AT/65AT".
For the transducers supported by each diagnostic ultrasound system, refer to the operation manual supplied with the diagnostic ultrasound system.
Note that some of the listed models may not be available in some regions.

*4 : The mouthpieces supplied with the TEE transducer can be sterilized by boiling, by autoclaving (temperature: 134°C, holding time: 5 min), or by using ethylene oxide gas (gas concentration: 20%, temperature: 55°C, humidity: ambient humidity, pressure: 167 kPa, holding time: 4 hours, aeration time: 12 hours).
Confirm that "AUTOCLAVABLE" is indicated on the mouthpiece.
After gas sterilization, perform aeration thoroughly to remove all traces of the gas from the surfaces of the mouthpiece.

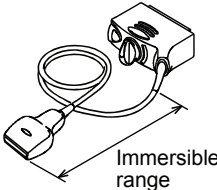
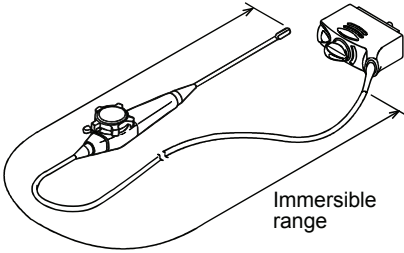
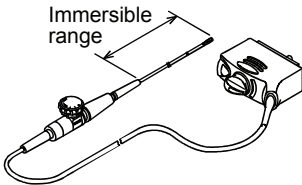
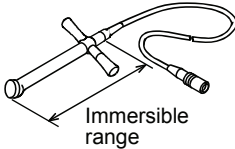
*5 : If a waterproof cover is placed over the transducer connector, the entire transducer can be immersed in water, cleaning solution, or disinfectant.

● Type A (PC-20M)

● Type B (PET-508MA)

● Type C (PET-510MB etc.)

● Type D (PLT-704AT etc.)



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